REMARKS

Claims 1-41 are pending in the application. Claims 1, 11, 17, 18, 22, 23, 38, 40, and 41 have been amended. Claim 5 has been canceled. Applicants respectfully request reconsideration and reexamination of the pending claims.

Claim Rejections – 35 U.S.C. § 102

Claims 1, 2, 5, 7, 11, 13, 17, 23, 25, 27, 31, 33, 38, and 39 are rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,690,103 ("Groth '103").

Amended independent Claim 1 calls for, among other things, a method of diagnosing cardiac syndromes including the act of calculating a risk of a cardiac syndrome based on the combination of indicators. Groth '103 does not teach or suggest, among other things, a method of diagnosing cardiac syndromes including the act of calculating a risk of a cardiac syndrome based on the combination of indicators.

Rather, Groth '103 discloses a system and method of providing decision support for early assessment of patients with suspected acute myocardial infarction ("AMI"). The system can determine if the patient experienced an AMI. If the patient has not experienced an AMI, the system can determine if the patient has minor myocardial damage ("MMD"). Col. 6, lines 16-23. MMD is representative of elevations of biochemical markers. Col. 1, lines 37-41. The detection of MMD indicates that the patient has a higher risk for subsequent cardiac events. Col. 1, lines 40-51. Groth '103 does not calculate the risk of a cardiac syndrome. It only determines if there is a higher or lower risk for a subsequent cardiac event based on whether or not MMD is detected. Accordingly, Claim 1 is allowable. Claims 2-17 depend on Claim 1, and are therefore allowable for at least the reasons Claim 1 is allowable.

Amended independent Claim 23 calls for, among other things, a diagnostic system comprising a fusion engine operable to ... calculate a risk of ACS based on a combination of the data received from the first and second modules. As noted above, Groth '103 does not teach or suggest this element. Rather, Groth '103 only determines if there is a higher or lower risk for a subsequent cardiac event based on whether or not MMD is detected. Accordingly, Claim 23 is allowable. Claims 24-36 depend on Claim 23, and are therefore allowable for at least the reasons Claim 23 is allowable.

Amended independent Claim 38 calls for, among other things, a method of diagnosing cardiac syndromes including the act of calculating a risk of a cardiac syndrome before an actual cardiac event has occurred based on the combination of the plurality of indicators. As noted above, Groth '103 does not teach or suggest this element. Rather, Groth '103 only determines if there is a higher or lower risk for a subsequent cardiac event based on whether or not MMD is detected. Accordingly, Claim 38 is allowable. Claim 39 depends on Claim 38, and is therefore allowable for at least the reasons Claim 38 is allowable.

Claims 1, 5, 6, 17, 23, 25, 26, 38, and 39 are rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 6,361,503 ("Starobin").

Amended independent Claim 1 calls for, among other things, a method of diagnosing cardiac syndromes including the act of acquiring data from a first type of diagnostic test and acquiring data from a second type of diagnostic test. Starobin does not teach or suggest, among other things, a method of diagnosing cardiac syndromes including the act of acquiring data from a first type of diagnostic test and acquiring data from a second type of diagnostic test. Rather, Starobin discloses a method of assessing cardiac ischemia in a patient to provide a measure of cardiovascular health in that subject. This assessment only uses ECG data, and not a second different type of data. Accordingly, Claim 1 is allowable. Claims 2-17 depend on Claim 1, and are therefore allowable for at least the reasons Claim 1 is allowable.

Amended independent Claim 23 calls for, among, other things, a diagnostic system comprising a first physiological activity acquisition module and a second physiological activity acquisition module different than the first physiological activity acquisition module. As noted above, Starobin only acquires data from a single type of acquisition module, i.e., an ECG module. Accordingly, Claim 23 is allowable. Claims 24-36 depend on Claim 23, and are therefore allowable for at least the reasons Claim 23 is allowable.

Amended independent Claim 38 calls for, among other things, a method of diagnosing cardiac syndromes including the act of acquiring data from a plurality of different diagnostic tests. As noted above, Starobin only acquires data from a single type of acquisition module, i.e., an ECG module. Accordingly, Claim 38 is allowable. Claim 39 depends on Claim 38, and is therefore allowable for at least the reasons Claim 38 is allowable.

Claim Rejections – 35 U.S.C. § 103

Claims 1, 2, 5-8, 11-14, 17, 23, 25-28, 31-34, 38, and 39 are rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 6,443,889 ("Groth '889") in combination with Groth '103.

To establish a *prima facie* case of obviousness under Section 103, three basic criteria must be met. *M.P.E.P.* § 2143. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior-art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure. *See M.P.E.P.* § 2143.1. Moreover, it is improper to combine references where the references teach away from their combination. *See M.P.E.P.* § 2145. The Office's proposed combination of references does **not** meet the above criteria with respect to the subject matter of the claims.

Amended independent Claim 1 calls for, among other things, a method of diagnosing cardiac syndromes including the act of calculating a risk of a cardiac syndrome based on the combination of indicators. Groth '889 does not teach or suggest, among other things, a method of diagnosing cardiac syndromes including the act of calculating a risk of a cardiac syndrome based on the combination of indicators.

Rather, Groth '889 discloses a system and method of providing decision support for early assessment of patients with suspected acute myocardial infarction ("AMI"). The system utilizes a trained and tuned artificial neural network that uses patient specific parameters 40, which are acquired from the patient shortly after entering a medical care facility, and AMI variables 42 to calculate decision regions 32, 52 (e.g., non-AMI, minor AMI, medium AMI, major AMI). Col. 5, line 61-col. 6, lines 65; Figs. 8a-8c. The AMI variables are used to determine which decision region 32, 52 the patient should be referred to at a specific point in time. Col. 5, lines 44-52. A second set of data can be acquired at a subsequent time and input into the system to determine which decision region 32, 52 the patient should be referred to at the subsequent time. Col. 11, line 63-col. 12, line 23. In other words, the system is used to determine whether the patient

suffered an AMI and the severity of the AMI to determine management and treatment options. Col. 12, lines 28-35. The system does not calculate a risk.

Groth '103 does not cure the deficiencies of Groth '889. Groth '103 does not teach or suggest, among other things, a method of diagnosing cardiac syndromes including the act of calculating a risk of a cardiac syndrome based on the combination of indicators. Rather, as noted above, Groth '103 only determines if there is a higher or lower risk for a subsequent cardiac event based on whether or not MMD is detected.

The combination of Groth '889 and Groth '103 do not teach or suggest all of the limitations of Claim 1. Accordingly, Claim 1 is allowable. Claims 2-17 depend on Claim 1, and are therefore allowable for at least the reasons Claim 1 is allowable.

Amended independent Claim 23 calls for, among other things, a diagnostic system comprising a fusion engine operable to ... calculate a risk of ACS based on a combination of the data received from the first and second modules. As noted above, Groth '889 and Groth '103 do not teach or suggest this element. Rather, Groth '889 discloses a system that determines whether the patient suffered an AMI and the severity of the AMI to determine management and treatment options. Groth '103 only determines if there is a higher or lower risk for a subsequent cardiac event based on whether or not MMD is detected.

The combination of Groth '889 and Groth '103 do not teach or suggest all of the limitations of Claim 23. Accordingly, Claim 23 is allowable. Claims 24-36 depend on Claim 23, and are therefore allowable for at least the reasons Claim 23 is allowable.

Amended independent Claim 38 calls for, among other things, a method of diagnosing cardiac syndromes including the act of calculating a risk of a cardiac syndrome before an actual cardiac event has occurred based on the combination of the plurality of indicators. As noted above, Groth '889 and Groth '103 do not teach or suggest this element. Rather, Groth '889 discloses a system that determines whether the patient suffered an AMI and the severity of the AMI to determine management and treatment options. Groth '103 only determines if there is a higher or lower risk for a subsequent cardiac event based on whether or not MMD is detected.

The combination of Groth '889 and Groth '103 do not teach or suggest all of the limitations of Claim 38. Accordingly, Claim 38 is allowable. Claim 39 depends on Claim 38, and is therefore allowable for at least the reasons Claim 38 is allowable.

Claims 9, 10, 15, 16, 29, 30, 35, and 36 are rejected under 35 U.S.C. § 103 as being unpatentable over Groth '889 in view of Groth '103 and further in view of U.S. Patent No. 6,059,724 ("Campell").

Claims 9, 10, 15, and 16 depend from independent Claim 1 and are allowable for at least the reasons set forth above with respect to Claim 1. As noted above, with respect to Claim 1, Groth '889 and Groth '103 do not teach or suggest, among other things, a method of diagnosing cardiac syndromes including the act of calculating a risk of a cardiac syndrome based on the combination of the plurality of indicators.

Campell does not cure the deficiencies of Groth '889 and Groth '103. Campell discloses a system for predicting the future health of an individual. The system acquires biomarker data for an individual and predicts an individual's future health based on statistically comparing the individual's set of biomarker values with a longitudinally-obtained database of sets of a large number of individual biomarker values for a large test population. Col. 6, lines 12-32. Biomarker data can be acquired over an individual's lifetime. Col. 6, lines 33-51. The system provides a quantitative estimate of the probability of an individual acquiring a specified biological condition within a specified period of time. Col. 6, lines 52-55.

There is no suggestion or motivation to combine the teachings of Groth '889, Groth '103, and Campell because each system is using different data for analysis and making very different conclusions. The system in Groth '889 and '103 is using artificial neural networks to determine, based on AMI-related biomarker data if a patient has experienced an AMI and what level of damage has occurred to determine management and treatment options. In contrast, the system in Campell acquires biomarker data over any length of time to provide a probability of an individual acquiring a biological condition within a certain period of time when compared to other individual biomarker data. One system (Groth '889 and Groth '103) uses present data to determine a past condition or event. The other system (Campell) uses present and past data of one individual to determine the probability of a future event when compared to data from other individuals. In addition, the Groth '889 and '103 system must determine if the patient presently has heart damage in order to inform medical personnel of proper treatment for the patient. In contrast, the system in Campell can not determine if the person currently has heart damage, which must be assessed immediately for prompt treatment as in Groth. The system in Campell is only capable of comparing a person's past and present biomarker data to determine the

probability of a future event. Using the system as in Campell on a patient that is in the hospital for chest pain would not tell the medical personnel how to provide adequate treatment to the patient as does the system inGroth '889 and '103.

For at least these reasons, Groth '889, Groth '103, and Campell do not provide the necessary motivation and suggestion to be combined. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claims 9, 10, 15, and 16 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, dependent Claims 9, 10, 15, and 16 are allowable.

Claims 29, 30, 35, and 36 depend from independent Claim 23 and are allowable for at least the reasons set forth above with respect to Claim 23. As noted above, with respect to Claim 23, Groth '889 and Groth '103 do not teach or suggest, among other things, a diagnostic system including a fusion engine operable to ... calculate a risk of ACS based on a combination of the data received from the first and second modules.

Campell does not cure the deficiencies of Groth '889 and Groth '103. As noted above with respect to Claims 9, 10, 15, and 16, there is no suggestion or motivation to combine the three references.

For at least these reasons, Groth '889, Groth '103, and Campell do not provide the necessary motivation and suggestion to be combined. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claims 29, 30, 35, and 36 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, dependent Claims 29, 30, 35, and 36 are allowable.

Claims 3, 4, 18-22, 40, and 41 are rejected under 35 U.S.C. § 103 as being unpatentable over Groth '889 in view of Groth '103 and further in view of U.S. Patent No. 6,394,952 ("Anderson") and Lachajewski.

Claims 3 and 4 depend from independent Claim 1 and are allowable for at least the reasons set forth above with respect to Claim 1. As noted above, with respect to Claim 1, Groth '889 and Groth '103 do not teach or suggest, among other things, a method of diagnosing cardiac syndromes including the act of calculating a risk of a cardiac syndrome based on the combination of the plurality of indicators.

Anderson does not cure the deficiencies of Groth '889 and Groth '103. Anderson does not teach or suggest, among other things, a method of diagnosing cardiac syndromes including

the act of calculating a risk of a cardiac syndrome based on the combination of indicators. Rather, Anderson discloses a system for reading test data from a test strip and software for converting the data into diagnostic or risk assessment information. Col. 2, lines 27-29. The system is to be used at the point of care where a rapid and accurate result is desired. Col. 11, lines 40-45. Specifically, the system is used for diagnosing or predicting conditions such as pregnancy, including ectopic pregnancy, pre-eclampsia, preterm labor or imminent delivery and fetal membrane rupture. Col. 15, lines 16-20. A patient sample is acquired and positioned on a test strip for testing by the system. Col. 16, lines 26-59. The patient sample on the test strip is read by a reflectance reader to determine the presence and/or quantity of analyte present in the sample. Col. 17, lines 34-55. The system outputs a disease risk index or medical diagnosis. Col. 11, lines 58-59. Anderson indicates that the system can provide a risk assessment for a patient, however, there is no indication that the system calculates a risk of a cardiac syndrome. Anderson does not provide any indication that the system actually calculates a risk value, and furthermore, does not provide any risk values in the examples in columns 35-41.

Lachajewski does not cure the deficiencies of Groth '889, Groth '103, and Anderson. Lachajewski also does not teach or suggest, among other things, a method of diagnosing cardiac syndromes including the act of calculating a risk of a cardiac syndrome based on the combination of indicators. Rather, Lachajewski discloses an adaptive control system for use with a printing press to control the setting of an ink control device that regulates the amount of ink applied to paper. Col. 3, lines 14-18. The system utilizes fuzzy logic, which includes the concept of fuzzy sets and membership functions to assess color quality of printed images. Col. 8, line 45-col. 9, line 14.

In addition, there is no suggestion or motivation to combine the teachings of Groth '889, Groth '103, Anderson, and Lachajewski. The system in Lachajewski works with a printing press, and is in no way related to medical-related systems. One having ordinary skill in the art would not look to printing systems to solve a problem with medical-related systems. In addition, the development of fuzzy logic systems require the membership functions and the diagnostic rules to be unique to the data being analyzed. The membership functions and the diagnostic rules for analyzing color quality can not be interchanged with the membership functions and the diagnostic rules for analyzing medical data. It would require undue experimentation for a person of ordinary skill in the medical arts to review the Lachajewski system and the membership

functions and the diagnostic rules related to color quality to come up with the membership functions and the diagnostic rules for analyzing medical data.

Furthermore, Groth '889, Groth '103, and Anderson only mention that fuzzy logic may be used in their respective systems. The three references do not specifically disclose the use of membership functions and rules, but rather disclose the use of neural networks. Neural networks and fuzzy logic are not necessarily interchangeable. A neural network must be trained with data, and, therefore, the analysis parameters can be constantly changing. Results may not always be consistent depending on the data upon which the neural network is trained. In contrast, the same membership functions and diagnostic rules are generated based on mathematical algorithms that are applied to the data in a fuzzy logic system to provide the results.

For at least these reasons, Groth '889, Groth '103, Anderson, and Lachajewski do not teach or suggest the subject matter of Claims 3 and 4 and do not provide the necessary motivation and suggestion to be combined. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claims 3 and 4 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, Claims 3 and 4 are allowable.

Independent Claim 18 calls for, among other things, a cardiac syndrome diagnostic system including a fusion engine operable to … calculate a risk of a cardiac syndrome based on a combination of the first and second sets of degrees of membership and a set of predetermined rules. As noted above, Groth '889, Groth '103, Anderson, and Lachajewski do not teach or suggest, among other things, a cardiac syndrome diagnostic system including a fusion engine operable to … calculate a risk of a cardiac syndrome based on a combination of the first and second sets of degrees of membership and a set of predetermined rules. Also, as noted above, Groth '889, Groth '103, Anderson, and Lachajewski can not be combined.

For at least these reasons, Groth '889, Groth '103, Anderson, and Lachajewski do not teach or suggest the subject matter of Claim 18 and do not provide the necessary motivation and suggestion to be combined. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claim 18 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, independent Claim 18 is allowable. Claims 19-22 depend from Claim 18, and are therefore allowable for at least the reasons Claim 18 is allowable.

Amended independent Claim 40 calls for, among other things, a method of determining a risk for a cardiac event in a patient including the act of comparing the output function value to a

plurality of output membership functions to calculate the patient's risk of a future cardiac event. As noted above, Groth '889, Groth '103, Anderson, and Lachajewski do not teach or suggest, among other things, a method of determining a risk for a cardiac event in a patient including the act of comparing the output function value to a plurality of output membership functions to calculate the patient's risk of a future cardiac event. Also, as noted above, Groth '889, Groth '103, Anderson, and Lachajewski can not be combined.

For at least these reasons, Groth '889, Groth '103, Anderson, and Lachajewski do not teach or suggest the subject matter of Claim 40 and do not provide the necessary motivation and suggestion to be combined. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claim 40 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, independent Claim 40 is allowable.

Amended independent Claim 41 calls for, among other things, a computer program including instructions that fuzzify, compute, combine, and defuzzify the indicators to calculate a patient's risk for a future cardiac event. As noted above, Groth '889, Groth '103, Anderson, and Lachajewski do not teach or suggest, among other things, a method of determining a risk for a cardiac event in a patient including the act of comparing the output function value to a plurality of output membership functions to calculate the patient's risk of a future cardiac event. Also, as noted above, Groth '889, Groth '103, Anderson, and Lachajewski can not be combined.

For at least these reasons, Groth '889, Groth '103, Anderson, and Lachajewski do not teach or suggest the subject matter of Claim 41 and do not provide the necessary motivation and suggestion to be combined. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claim 41 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, independent Claim 41 is allowable.

Claims 3, 4, 18-22, 24, 37, 40, and 41 are rejected under 35 U.S.C. § 103 as being unpatentable over Groth '103 in view of Lachajewski.

Claims 3 and 4 depend from independent Claim 1 and are allowable for at least the reasons set forth above with respect to Claim 1. As noted above, with respect to Claim 1, Groth '103 and Lachajewski do not teach or suggest, among other things, a method of diagnosing cardiac syndromes including the act of calculating a risk of a cardiac syndrome based on the combination of indicators. Also, as noted above, Groth '103 and Lachajewski can not be combined.

For at least these reasons, Groth '889 and Lachajewski do not teach or suggest the subject matter of Claims 3 and 4 and do not provide the necessary motivation and suggestion to be combined. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claims 3 and 4 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, Claims 3 and 4 are allowable.

Independent Claim 18 calls for, among other things, a cardiac syndrome diagnostic system including a fusion engine operable to ... calculate a risk of a cardiac syndrome based on a combination of the first and second sets of degrees of membership and a set of predetermined rules. As noted above, Groth '103 and Lachajewski do not teach or suggest, among other things, a cardiac syndrome diagnostic system including a fusion engine operable to ... calculate a risk of a cardiac syndrome based on a combination of the first and second sets of degrees of membership and a set of predetermined rules. Also, as noted above, Groth '103 and Lachajewski can not be combined.

For at least these reasons, Groth '103 and Lachajewski do not teach or suggest the subject matter of Claim 18 and do not provide the necessary motivation and suggestion to be combined. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claim 18 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, independent Claim 18 is allowable. Claims 19-22 depend from Claim 18, and are therefore allowable for at least the reasons Claim 18 is allowable.

Claim 24 depends from independent Claim 23, and is therefore allowable for at least the reasons Claim 23 is allowable. As noted above, with respect to Claim 23, Groth '103 and Lachajewski do not teach or suggest, among other things, a diagnostic system including a fusion engine operable to ... calculate a risk of ACS based on a combination of the data received from the first and second modules. Also, as noted above, Groth '103 and Lachajewski can not be combined.

For at least these reasons, Groth '103 and Lachajewski do not teach or suggest the subject matter of Claim 24 and do not provide the necessary motivation and suggestion to be combined. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claim 23 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, Claim 24 is allowable.

Independent Claim 37 calls for, among other things, a method for diagnosing acute cardiac syndromes including the act of calculating a risk of ACS using fuzzy logic rules. As noted above, Groth '103 and Lachajewski do not teach or suggest, among other things, a method for diagnosing acute cardiac syndromes including the act of calculating a risk of ACS using fuzzy logic rules. Also, as noted above, Groth '103 and Lachajewski can not be combined.

For at least these reasons, Groth '103 and Lachajewski do not teach or suggest the subject matter of Claim 37 and do not provide the necessary motivation and suggestion to be combined. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claim 37 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, independent Claim 37 is allowable.

Amended independent Claim 40 calls for, among other things, a method of determining a risk for a cardiac event in a patient including the act of comparing the output function value to a plurality of output membership functions to calculate the patient's risk of a future cardiac event. As noted above, Groth '103 and Lachajewski do not teach or suggest, among other things, a method of determining a risk for a cardiac event in a patient including the act of comparing the output function value to a plurality of output membership functions to calculate the patient's risk of a future cardiac event. Also, as noted above, Groth '103 and Lachajewski can not be combined.

For at least these reasons, Groth '103, Anderson, and Lachajewski do not teach or suggest the subject matter of Claim 40 and do not provide the necessary motivation and suggestion to be combined. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claim 40 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, independent Claim 40 is allowable.
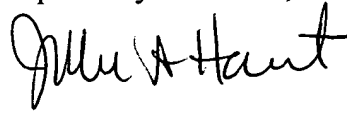
Amended independent Claim 41 calls for, among other things, a computer program including instructions that fuzzify, compute, combine, and defuzzify the indicators to calculate a patient's risk for a future cardiac event. As noted above, Groth '103 and Lachajewski do not teach or suggest, among other things, a method of determining a risk for a cardiac event in a patient including the act of comparing the output function value to a plurality of output membership functions to calculate the patient's risk of a future cardiac event. Also, as noted above, Groth '103 and Lachajewski can not be combined.

For at least these reasons, Groth '103 and Lachajewski do not teach or suggest the subject matter of Claim 41 and do not provide the necessary motivation and suggestion to be combined. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claim 41 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, independent Claim 41 is allowable.

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully request entry of this Amendment and allowance of Claims 1-4 and 6-41. The undersigned is available for telephone consultation at any time.

Respectfully submitted,

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